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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,040	01/26/2006	David Harold Drewry	PR60418USW	9316

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EXAMINER	
MABRY, JOHN	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
05/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,040	DREWRY ET AL.	
	Examiner	Art Unit	
	John Mabry, PhD	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/29/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *Claims 1, 3, 5, 8-12, 14-41 and 43* is/are pending in the application.

4a) Of the above claim(s) *2,4,6,7,13,42 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *Claims 1, 3, 5, 8-12, 14-41 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Examiner's Response

Applicant's response on April 29, 2008 filed in response to the Election/Restriction dated April 4, 2008 has been received and duly noted. The Examiner acknowledges Applicants' election of Group I without traverse.

Thus, the restriction requirement is deemed proper and **FINAL**.

In view of this response, the status of the rejections/objections of record is as follows:

Specification Objections

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The current title is “Chemical Compounds". Examiner suggests a title that directed towards elected group.

The Specification is objected to because of the following informalities: Example 29 is overlapping with the data and part of the structure is missing on page 29. Appropriate correction is required.

Claim Objections

Claim 43 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 43 claims “any of claims 1-40”. Examiner interprets that claim 43 can depend on more than one of the previous claims (claims 1-40).

Claims 1, 3, 5, 8-12, 14-41 and 43 are objected to because claims are drawn to non-elected subject matter. For example, when m=0, R1 cannot be phenyl. According to the elected group, R1 must be phenyl (therefore m has to equal 1). There are several more similar examples pertaining to this issue.

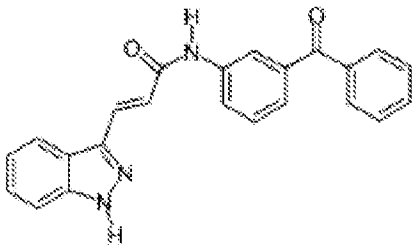
Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 8-12, 14-41 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recites and claims the limitation "(2E)-N-(3-benzoylphenyl)-3-(1H-indazol-3-yl)-2-propenamide " in the twelfth (12^{th}) specie in claim 40 (see below).



There is insufficient antecedent basis for this limitation in the claim. According to claim 1, r must equal at least 1 which means Q1 has to equal -CH2-C(O)-. This particular species would require r to equal 0. Thus, the required elected species for the restriction requirement does not fall within the scope of the elected group. Additionally, claims 9 and 15 require m=0. When m=0, R1 cannot be phenyl. There are several more similar examples pertaining to this issue. The Examiner respectfully requests that Applicant carefully review the claims and correct these errors in order to avoid rejections.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 8-12, 14-41 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Q1 being phenyl, Q2 being alkyl, cycloalkyl, -OH, alkyloxy, pyridinyl, phenyl, pyrrolidinyl, pyrimidinyl, piperidinyl, isoxazolyl, benzothiazolinyl and R1/R2 together with N to form morpholinyl, piperazinyl, does not reasonably provide enablement for Q1 and Q2 being all claimed aryl, arylene, heteroaryl, heteroarylene, heterocyclic groups as claimed and R1/R2

together with N to form all claimed N containing heteroaryl and heterocyclic groups as claimed.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The Specification does not provide any support for said variables at Q1, Q2 and R1/R2 positions. Pages 33-34 of the Specification describe starting materials and methods for synthesis of compounds wherein Q1, Q2 and R1/R2 as previously mentioned, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where Q1, Q2 and R1/R2 as listed above.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims: Scope of the compounds. Owing to the range of many variables,

millions of highly substituted 1H-indazole compounds are embraced.

(2) The nature of the invention: The invention is a highly substituted 1H-indazole compounds.

(3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical reactivity (which is affected by determinants such as substituent effects, steric effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. Pages 33-34 of the Specification describes starting materials and methods for synthesis of compounds wherein Q1 being phenyl, Q2 being alkyl, cycloalkyl, -OH, alkyloxy, pyridinyl, phenyl, pyrrolidinyl, pyrimidinyl, piperidinyl, isoxazolyl, benzothiazolinyl and R1/R2 together with N to form morpholinyl, piperazinyl, does not reasonably provide enablement for Q1 and Q2 being all claimed aryl, arylene, heteroaryl, heteroarylene, heterocyclic groups as claimed and R1/R2 together with N to form all claimed N containing heteroaryl and heterocyclic groups as claimed. There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed

of formula. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here…As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court *in re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: These compounds are substituted 1H-indazole compounds wherein Q1 and Q2=phenyl which are well documented in the art. So far as the examiner is aware, no substituted 1H-indazole compounds of general formula I wherein Q1, Q2 and R1/R2 as aforementioned of any kind have been made or used.

It is not trivial to experimentally interchange any and all of the many substituents

that exist. As described by F. Zaragoza Dörwald, most organic syntheses fail initially and chemical research is highly inefficient due to chemists spending most of their time "finding out what went wrong and why". Therefore, most syntheses of organic compounds are labor-intensive and demanding. Additionally, most final synthetic routes to desired organic molecules are usually very different from initially planned routes. A highly skilled chemist can agree that for many successful organic compounds made, many failures are encountered and experimental repetition is common. This also contributes to the burden and unpredictability of the syntheses of said compounds. (see “Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design" 2005 Wiley-VCH Verlag GmbH & Co. KGaA, Wienheim.

(6) Working Examples: Applicant shows examples 1-41 (on pages 41-66) but no working examples were shown wherein Q1, Q2 and R1/R2 as aforementioned, along with claimed substituents, have been made or used of any kind.

(7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.

(8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claims 1, 3, 5, 8-12, 14-41 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for salts, does not reasonably provide enablement for physiological functional derivatives, hydrates and solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to physiological functional derivatives, hydrates and solvates. But the numerous examples presented all failed to produce a hydrate or solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

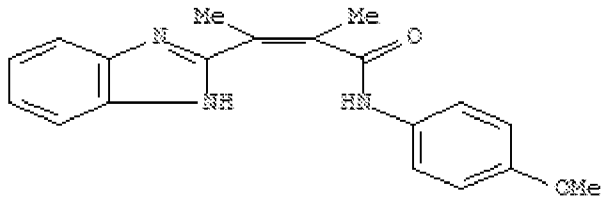
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5, 8-12, 14-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaur (Indian Journal of Heterocyclic Chemistry 2000, 9, 227-230).

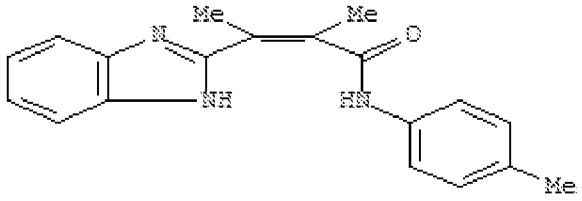
The instant application claims compounds and pharmaceutical compositions of Formula I wherein, R2, R5=H, R3, R4=CH3 and R1=phenyl-4-methoxy.

Scope & Content of Prior Art MPEP 2141.01

Gaur discloses compounds of Formula I wherein, R2, R5=H, R3, R4=CH3 and R1=phenyl-4-methoxy (R1=-(Q)-(Q1)-(Q2) and m=1 and p, n=0 (see page 228).

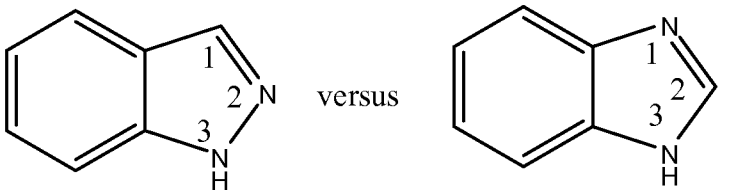


Gaur also discloses compounds of Formula I wherein, R2, R5=H, R3, R4=CH3 and R1=phenyl-4-methyl (R1=-(Q)-(Q1)-(Q2) and m=1 and p, n=0 (see page 228).



Differences between Prior Art & the Claims MPEP 2141.02

The instant application differs from Gaur at the 1 and 2 positions: Applicant's 1H-indazole versus Gaur's 1H-benzo[d]imidazole. These are considered positional isomers (i.e. structural analogues).



1*H*-indazole 1*H*-benzo[*d*]imidazole

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

There is little difference between the 1C=N2 of Applicant as compared at the 1N=C2 of Gaur regarding the claimed structure of Formula I. It is well established that

position isomers are prima facie structurally obvious even in the absence of a teaching to modify. The isomer is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing the position isomers. This circumstance has arisen many times. See: *Ex parte Englehardt,* 208 USPQ 343, 349; *In re Mehta,* 146 USPQ 284, 287; *In re Surrey*, 138 USPQ 67; *Ex Parte Ullyot,* 103 USPQ 185; *In re Norris,* 84 USPQ 459; *Ex. Parte Naito,* 168 USPQ 437, 439; *Ex parte Allais,* 152 USPQ 66; *In re Wilder,* 166 USPQ 545, 548; *Ex parte Henkel,* 130 USPQ 474; *Ex parte Biel,* 124 USPQ 109; *In re Petrzilka,* 165 USPQ 327; *In re Crownse,* 150 USPQ 554; *In re Fouche,* 169 USPQ 431; *Ex parte Ruddy,* 121 USPQ 427; *In re Wiechert,* 152 USPQ 249, *In re Shetty,* 195 USPQ 753; *In re Jones,* 74 USPQ 152, 154. There may be others as well. Thus, said claims are rendered obvious by Gaur et al.

For example, "Position isomerism has been used as a tool to obtain new and useful drugs" (*Englehardt*) and "Position isomerism is fact of close structural similarity" (*Mehta*, emphasis in the original). Note also *In re Jones,* 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to prima facie obviousness"; one of those listed is "adjacent homologues and structural isomers". Position isomers are the basic form of close "structural isomers." Similar is *In re Schechter and LaForge,* 98 USPQ 144, 150, which states "a novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds." Note also

In re Deuel 34 USPQ2d 1210, 1214 which states, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds…a known compound may suggest it analog or isomers, either geometric (cis v. trans) or position isomers (e.g. *ortho v. para*)." See also MPEP 2144.09, second paragraph. Further, the reference provides for the ring being substituted in any position.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re* Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at___, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

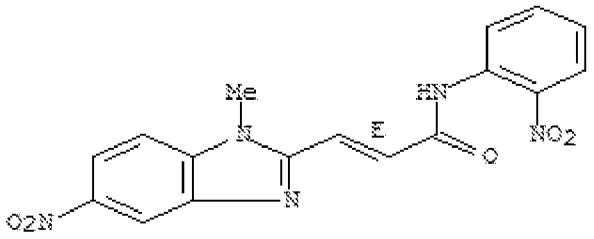
(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § 2143 for a discussion of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § 2144- §2144.09 for additional guidance regarding support for obviousness determinations.

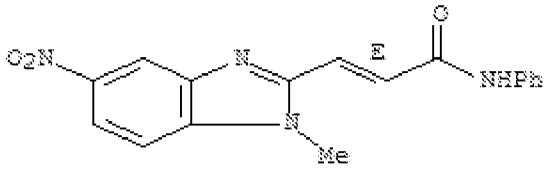
The aforementioned reasons above describe rationales that support a conclusion of obviousness based upon the KSR International Co. v.Teleflex Inc. decision. At least letter (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success – rationale is supported above.

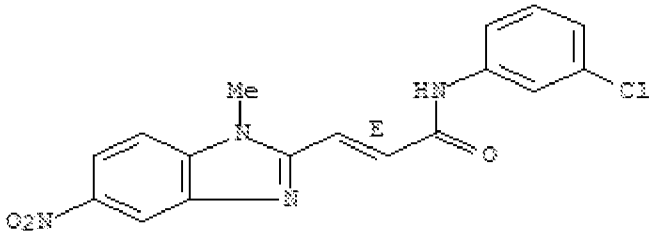
Claims 1, 3, 5, 8-12, 14-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omar (Zeitschrift fuer Naturforschung, Teil B: Anorganische Chemie, Organische Chemie 1979, 34B, 1427-1430).

The instant application claims compounds and pharmaceutical compositions of Formula I wherein, R5=NO2, R2, R3, R4=H and R1=phenyl-2-nitro (R1=-(Q)-(Q1)-(Q2) and m=1 and p, n=0.

Omar discloses compounds of Formula I wherein, R5=NO2, R2, R3, R4=H and R1=phenyl-2-nitro (R1=-(Q)-(Q1)-(Q2) and m=1 and p, n=0 (see Table I, page 1429).







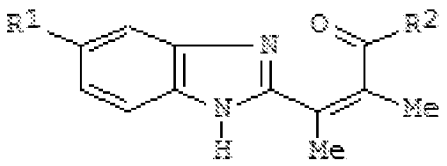
And R1/R2 of claimed Formula I is: -NH-(CH2)2OH, -NH-(CH3)2, -NH-(CH2)3CH3, -N(C2H5)2, morpholinyl, piperidinyl, pyrrolidinyl and several other derivatives as claimed (see entire Table I).

The instant application is obvious over Omar for the reasons as previously mentioned in the rejection over Gaur with one additional exception – Omar discloses the N-methyl 1H-indazole when the instant application claims the N-H 1H-indazole. An N-H versus an N-CH3 is considered obvious variants (see *Ex parte* Bluestone 135 USPQ 199).

Claims 1, 3, 5, 8-12, 14-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shetgiri et al (Indian J. Chem., Sect. B: Org. Chem. Including Med. Chem. 1999, 38B, 312-316).

The instant application claims compounds and pharmaceutical compositions of Formula I wherein, R5=H, Cl, R3, R4=CH3 and R1 and R2 combine with N to form heterocycles: morpholine, piperidine

Shetgiri claims compounds and pharmaceutical compositions of Formula I wherein, R5=H, Cl, R3, R4=CH3 and R1 and R2 combine with N to form heterocycles: morpholine, piperidine (see Scheme I, page 313, compounds 5A and 5B, page 313-314).



Where R2 of the above structure is piperazine, dimethyl amine, morpholine, piperidine and diphenylamine.

The instant application is obvious over Shetgiri for the reasons as previously mentioned in the rejection over Gaur.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry, PhD/
Examiner
Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625